REMARKS

I. Preliminary Remarks

Claim 26 is amended with this response for clarification purposes by deletion of "the" before "genomic DNA" and inserting "total" instead. Claim 47 is amended with this response by inserting "total" before "genomic DNA" for clarification purposes.

II. Patentability Arguments

A. The Rejection of Claims 26, 41-46, and 54 Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn.

At page 4 of the office action, the Examiner rejected claims 26, 41-46, and 54 under 35 U.S.C., first paragraph, as failing to comply with the written description requirement allegedly because the claims contain "total genomic DNA" limitation that the Examiner asserts is not supported by the specification. The Examiner argues that "the specification at pages 30-32 only provides support for the broad genus of the term "genomic DNA" and no contemplation of the species "total genomic DNA" has been disclosed." Applicant brings to the Examiner's attention that in paragraph 8 of subsection 3(a) of Section 2163, MPEP provides:

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

Methods of isolating total genomic DNA were known at the time of filing of the instant application. With respect to the term "total genomic DNA," Applicant submits that in view of the working examples set out in the specification which shows the use of total genomic DNA and the fact that the methods for isolating total genomic DNA are described in the specification, one of ordinary skill in the art would recognize that Applicant had in fact described and used "total genomic DNA" regardless of whether or not the term "total" was used.

By way of illustrative example, Applicant directs the Examiner to the first full paragraph at page 31 of the specification as filed, wherein Applicant writes "isolated, purified genomic DNA is isolated from a tumor or cell culture is then is preferably mechanically sheared . . . to render high molecular weight DNA fragments of about 20-25kb." Applicant further directs the Examiner to Example 5, entitled "Transfection of LM-IL-2K^b Cells ***with Genomic DNA*** from B16 Melanoma cells" (emphasis added). In the first paragraph of the Example, at page 48, Applicant writes "High molecular weight ***DNA isolated*** from B16 cells was used for the transfection of LM-IL-2K^b cells, ***using the method described by Wigler*** et al. (1978) Cell 14: 725-731 . . ." (enclosed as Exhibit A).

Wigler et al. is entitled "Biochemical transfer of single-copy eukaryotic genes using ***total cellular DNA*** as donor" (emphasis added). Applicant isolated DNA by using the method of Wigler (see above, page 48 of the specification). Therefore, it is clear to a person skilled in the relevant art that Applicant isolates total genomic DNA in Example 5 and uses the DNA in the claimed methods.

Because Applicant provides detailed support for "total genomic DNA" and because a person of ordinary skill in the art would know that Applicant was in possession

of the invention as claimed, Applicant submits that the claims meet the written support requirement of 35 U.S.C. § 112, first paragraph and therefore, rejection of claims 26, 41-46, and 54 may be properly withdrawn and such withdrawal is requested.

B. The Rejections of Claims 26, 41-46 and 54 Under 35 U.S.C. § 103(a) Should be Withdrawn

At page 5 of the office action, the Examiner alleges that the application currently names joint inventors. This assertion is in error. As can be seen from the filing receipt for the present patent application (a copy of which is enclosed), the application has only one inventor, Edward P. Cohen.

At page 6 of the office action, the Examiner alleges that claims 26 and 41-54 are unpatentable over US Patent Application 2002/0085997 to Schmidt et al. ("Schmidt") in view of Sun et al. in Cancer Gene Ther. 2(3): 183-190, 1995 ("Sun") and U.S. patent 6,277,368 to Hiserodt et al., filed on October 29, 1996 and issued on August 21, 2001 ("Hiserodt") because according to the Examiner, the Schmidt/Sun/Hiserodt combination renders instant claims 26 and 41-54 obvious under 35 U.S.C. 103(a).

As a matter of law, claims would be obvious only if the combination of Schmidt/Sun/Hiserodt teaches or suggests the present invention. Furthermore, the Examiner must show that a person of ordinary skill in the art had a motivation to combine teachings of Schmidt with those of Sun and Hiserodt at the time Applicant invented the claimed invention. However, Applicant respectfully submits that there was no motivation to combine the three references for the following reasons and also that the combination of the three references fails to teach or suggest the claimed invention.

At page 7 of the office action, the Examiner characterized Schmidt as teaching "a method of treating tumors by administering a composition that contains tumor cells at least some of which contain at least one MHC-1 haplotype of the patient of the cells surface and which are charged with one or more peptides binding to the MHC-I molecule in such a way that the tumor cells are recognized as foreign by the patient's immune system in context with peptides and trigger a cellular immune response. At page 8 of the office action, the Examiner admits that "Schmidt does not teach transfecting antigen-presenting cells with genomic DNA or sheared genomic DNA from neoplasm such that some gene products represent tumor-associated T-cell epitopes."

Schmidt defines its invention as "a tumour vaccine for administering to a patient, *consisting of tumour cells* which themselves present *peptides* derived from tumour antigens in the HLA context and at least some of which have at least one MHC-I-haplotype of the patient on the cell surface and which are charged with one or more *peptides* a) and/or b) in such a way that the tumour cells are recognized as foreign" (Paragraph 0023 of page 2). In contrast to Schmidt, the instant claims do not, *inter alia*, encompass methods utilizing tumour cells as antigen-presenting cells.

Schmidt also fails to disclose or suggest an antigen-presenting cell that expresses at least one class I MHC or class II MHC determinant that is syngeneic and at least one class I MHC or class II MHC determinant that is allogeneic. Further, Schmidt does not disclose antigen-presenting cells selected from the group consisting of professional antigen-presenting cells and facultative antigen-presenting cells; and transfected with genomic DNA isolated from the tumor cells of the animal.

Furthermore, Applicant submits that Schmidt actually teaches away from the instant invention. At page 2, in paragraph [0021], Schmidt specifically states: "*in contrast to approaches* in which the tumour antigen . . . is presented on the cell surface by the fact that it has been transfected with a DNA coding for the protein, . . . the intention is to provide a vaccine which triggers an efficient immune response whilst being simpler to manufacture." Thus, Schmidt teaches away from a method comprising transfection of antigen-presenting cells with DNA. Therefore, a person skilled in the relevant art would be discouraged by Schmidt to combine any of Schmidt teaching with other teachings comprising DNA transfection.

At page 8 of the office action, the Examiner characterized Sun as teaching cytokine-secreting fibroblasts transfected with sheared, unfractionated genomic DNA from different mouse neoplasms as a method to induce an antitumor immune response in the animal. The Examiner further states that at page 189, in the right column, Sun teaches "co-expression of allogeneic antigens augmented the cells' immunogenic properties as it protected the recipients against the growth of the modified cells." Sun does not teach or suggest an antigen-presenting cell expressing at least one class I MHC or class II MHC determinant that is syngeneic and at least one class I MHC or class II MHC determinant that is allogeneic to a vaccine recipient as is presently claimed. In summary, given the teaching against use of transfection with DNA encoding tumor antigens, there is no motivation to combine teachings of Schmidt and Sun, and further, Sun does not teach an antigen-presenting cell coexpressing syngeneic and allogeneic determinants as presently claimed.

At page 9 of the office action, the Examiner characterized Hiserodt as "teaching development of a cellular composition and method for using it in cancer immunotherapy, particularly in human patients, see Abstract, lines 1-3." Hiserodt does not teach or suggest that a vaccine can be made by transforming an antigen-presenting cell expressing at least one class I MHC or class II MHC determinant that is syngeneic and at least one class I MHC or class II MHC determinant that is allogeneic to a vaccine recipient with tumor genomic DNA. Thus, Hiserodt does not remedy deficiencies of Schmidt and Sun.

In summary, there is no motivation to combine teachings of Schmidt with those of Sun and Hiserodt. Further, the combination of references does not teach or suggest the subject matter of the present claims. Therefore, the combination cannot render the claims obvious as a matter of law. Therefore, the rejection under 25 U.S.C. 103(a) can be properly withdrawn and the withdrawal is respectfully requested.

Conclusion

Applicant respectfully submits that claims, as currently amended, are in condition for allowance and early notification thereof is requested. If in the interest of expediting prosecution, the Examiner has questions or comments he is invited to telephone the undersigned at the indicated telephone number.

Respectfully submitted,

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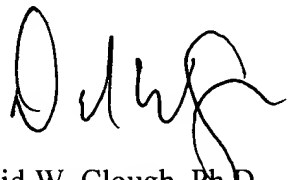
By: 

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